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Centers for Disease Control and Prevention
National Center for Infectious Diseases
Select Agent Transfer Program
1600 Clifton Road NE.
Mailstop E-79
Atlanta, Georgia 30333

Docket No. 02-088-1
Regulatory Analysis and Development
PPD, APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, Maryland 20737-1238.

RE: CDC Final Interim Rules for 42 CFR Part 73 and 42 CFR Part 1003; USDA Docket No. 02-088-1,

The Harvard Committee on Microbiological Safety (COMS) is the Institutional Biosafety Committee for Harvard University and eight of its Boston area affiliated hospitals. As such the Committee deals with hundreds of investigators and makes Biosafety judgments on over 300 scientific projects a year.

As representatives of a Committee largely responsible for the implementation and compliance with regulations governing the handling of select agents we offer the following comments regarding the CDC and USDA Final Interim Rules on the Possession, Use, and Transfer of Select Agents and Toxins.

1. **We would appreciate clarification as to the meaning of "any individual who owns or controls the entity" in the context of an academic institution.**

   This phrase appears repeatedly though out the Interim Rules but is not further defined (for instance CDC § 73.0 (b)(2) or USDA § 310.0(b)] In context the individual is NOT the Responsible Official. Context: ". . . the Responsible Official and any individual who owns or controls the entity." The "owner" appears to be in a position to supervise the Responsible Official.

2. **We recommend CDC and APHIS establish an appeals process should a dispute arise as to whether a modified biological agent or toxin is or is not a select agent. Appeals would be submitted to a panel of knowledgeable scientists and CDC representatives.**

   An appeals process would address an increasingly common problem with attenuated strains of select agents. Some genetic modifications increasing the attenuation of agents presently deemed exempt are being judged non-exempt by CDC representatives. Because of the expense and disruption involved in conforming to select agent rules investigators are abandoning studies with, and discarding, agents incorrectly deemed select agents by the CDC.

   We note the USDA has established an appeal process for animal agents and toxins and for overlap agents and toxins in § 121.3(g)(4), although no similar appeal provisions apply to plant agents and toxins in § 331.3 nor CDC § 73.5 or § 73.6.

3. **To prevent destruction of valuable historical, archival or educational materials containing Select Agents or toxins we suggest the regulations include a provision for their transfer to**

registered facilities, perhaps associated with the source entity, without full registration by the source.

4. **We recommend CDC, APHIS and the Department of Justice coordinate their Select Agent and toxin activities through a single office.**

   It is crucial to the efficient registration and monitoring of entities engaged in research with select agents that the rules pertaining to Select Agents should be consistent, regardless of whether the particular situation is regulated by USDA, DHHS, Commerce, Transportation or some combination, thereof. Inconsistencies in language or interpretation burden those who earnestly seek to comply with the regulations.

5. **We suggest CDC define the term "access" as the ability to come in physical contact with a primary container of the Select biological agent or toxin rather than contact with a secured secondary container such as a locked freezer.**

   If access is not clearly and narrowly defined, we anticipate that future inspections or Select Agent application reviews would result in widely differing judgments about the adequacy of security.

6. **We recommend broadening the definition of "entity" to permit a Responsible Official to discharge his/her responsibilities at several adjacent addresses.**

   Addresses are generally used to facilitate mail deliveries, not to establish areas of responsibility.

7. **If it is decided to incorporate NIH Recombinant DNA Guidelines and the NIH/CDC "Biosafety in Microbiological and Biomedical Laboratories" into the Final Rule we recommend the most current versions be specified.**

   By specifying the most current version of these documents, out of date guidance would be supplanted by the most recent.

   We note that USDA regulations mandate additional precautions when studies involve agricultural agents. We encourage CDC and APHIS to develop joint biological safety guidelines for Select agents and toxins to supplant the BMBL and NIH Guidelines.

8. **We recommend laboratory inspections be carried our by a Biosafety Officer designated by and reporting to the Responsible Official rather than the Responsible Official him/herself.**

   Biosafety Officers with their specialized knowledge and experience are more appropriate for this task than the more broadly experienced Responsible Official. The Biosafety Officer would register with DHHS and undergo a security risk assessment.

9. **We recommend the Responsible Official be broadly responsible for compliance with all provisions of the regulation, but the institution should be held to performance criteria, rather than specific procedures.**

   The RO should have latitude in how best to accomplish the requirements of the Rule (i.e.: Security assessment by outside security professional, inspections performed by other personnel at the institution, inspections while escorted by those authorized to access Select Agents, the ability to hold investigators accountable for aspects of the Rule, etc.).

10. **Several lesser issues**:
    a. Federal Register page 76894, last sentence: "Finally, the entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified." **We request clarification of the phrase "certain records and databases."**
    b. "Federal Register page 76895, under *Costs:* "In general, entities are adhering to guidance in the "Biosafety in Microbiological and Biomedical Laboratories (BMBL)," 4th Edition, as applicable to their specific biosafety level category (e.g., BSL2, BSL3, BSL4) category." **We note that the BMBL and NIH guidelines require BSL2 and BSL3 laboratories to post biohazard signs on access doors listing the agents present in the laboratory. This requirement may compromise laboratory security.**

We wish to emphasize our great appreciation for the efforts made by CDC and APHIS to generate a practical response to the threat of Bioterrorism. As institutions we are committed to providing a safe and secure environment within which to conduct research. Clarity and consistency in the final regulations can only enhance our abilities to comply and provide the greatest level of assurance to the public.

We look forward to working with you in the future.

Sincerely yours,

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